

I hereby certify that, on the date shown below, this correspondence is being:
☒ deposited with the United States Postal Service in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,
☐ under 37CFR § 1.8(a), with sufficient postage as first class mail, or
☒ under 37CFR § 1.10, as "Express Mail Post Office to Addressee" Mailing Label No.
EV 324 303 812 US,
☐ transmitted by facsimile to the Patent and Trademark Office, Fax Number _____

PATENT

Atty. Docket No.
AR02366USACON2

Date: August 20, 2003 By: _____

Lois E. Miller

CN 27777

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: George GUITTARD et al.

Serial No.: herewith

Filed: herewith

For: METHOD FOR MANAGEMENT OF
INCONTINENCE

Art Unit: to be assigned

Examiner: not yet assigned

Mail Stop: Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750 the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750 the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of references **BK-BZ** and **CB-CF** listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of the following references listed on the attached Form PTO-1449 are **NOT** enclosed herewith:

☐ In view of the voluminous nature of references _____, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☒ Copies of references **AA-BJ** and **CA** are not provided because they were previously cited or submitted to the Office in prior applications:

USSN: 09/785,805, filed 02/16/01, (pending);

USSN: 09/280,309, filed 03/29/99, (Now Patent 6,262,115);

USSN: 08/806,773, filed 02/26/97 (Now Patent 5,912,268);

USSN: 08/706,576, filed 09/05/96 (Now Patent 5,840,754);

USSN: 08/445,849, filed 05/22/95 (Now Patent 5,674,895).

☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:


☒ Attached are copies of PCT Search Reports from corresponding PCT applications PCT/US96/06639 and PCT/IB98/01982.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,

Dated: August 19, 2003
ALZA Corporation
1900 Charleston Road Bldg. M10-3
Mountain View, CA 94043-7210
650-564-5171


Robert R. Keller
Registration No. 46,950
Attorney for the Applicants

Enclosures:

1. PTO FORM 1449 (3 sheets)
2. PCT Search Report dated August 13, 1996 (3 pages);
3. PCT Search Report dated April 28, 1999 (3 pages);
4. References **BK – BZ** and **CB – CF** (21 references).

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: AR02366USACON2	SERIAL NO.: TO BE ASSIGNED	
INFORMATION DISCLOSURE STATEMENT FOR PATENT <i>(Use several sheets if necessary)</i>				APPLICANT: George GUITTARD, et al.		
				FILING DATE: Herewith	GROUP: to be assigned	
U.S. PATENT DOCUMENTS						
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	6,262,115	07/17/01	GUITTARD <i>et al.</i>		
	AB	6,124,355	09/26/00	GUITTARD <i>et al.</i>		
	AC	5,912,268	06/15/99	GUITTARD <i>et al.</i>		
	AD	5,840,754	11/24/98	GUITTARD <i>et al.</i>		
	AE	5,811,126	09/22/98	KRISHNAMURTHY		
	AF	5,674,895	10/07/97	GUITTARD <i>et al.</i>		
	AG	5,399,359	03/21/95	BAICHWAL		
	AH	4,902,514	02/20/90	BARCLAY <i>et al.</i>		
	AI	4,863,456	09/05/89	STEPHENS <i>et al.</i>		
	AJ	4,853,229	08/01/89	THEEUWES		
	AK	4,824,675	04/25/89	WONG <i>et al.</i>		
	AL	4,816,263	03/28/89	AYER <i>et al.</i>		
	AM	4,783,337	11/08/88	WONG <i>et al.</i>		
	AN	4,752,470	06/21/88	MEHTA		
	AO	4,721,613	01/26/88	URQUHART <i>et al.</i>		
	AP	4,612,008	09/16/86	WONG <i>et al.</i>		
	AQ	4,434,153	02/28/84	URQUHART <i>et al.</i>		
	AR	4,327,725	05/04/82	CORTESE <i>et al.</i>		
	AS	4,285,987	08/25/81	AYER <i>et al.</i>		
	AT	4,200,098	04/29/80	AYER <i>et al.</i>		
	AU	4,111,202	09/05/78	THEEUWES		
	AV	4,093,709	06/06/78	CHOI <i>et al.</i>		
	AW	4,088,864	05/09/78	THEEUWES <i>et al.</i>		
	AX	4,083,949	04/11/78	BENEDIKT		
	AY	4,079,038	03/14/78	CHOI <i>et al.</i>		
	AZ	4,070,347	01/24/78	SCHMITT		
	BA	4,066,747	01/03/78	CAPOZZA		
	BB	4,063,064	12/13/77	SAUNDERS <i>et al.</i>		
	BC	3,992,518	11/16/76	CHEIN <i>et al.</i>		
EXAMINER			DATE CONSIDERED			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: AR02366USACON2	SERIAL NO.: TO BE ASSIGNED
INFORMATION DISCLOSURE STATEMENT FOR PATENT <i>(Use several sheets if necessary)</i>				APPLICANT: George GUITTARD, et al.	
				FILING DATE: Herewith	GROUP: to be assigned

U.S. PATENT DOCUMENTS							
	BD	3,962,414	06/08/76	MICHAELS			
	BE	3,916,899	11/04/75	THEEUWES <i>et al.</i>			
	BF	3,845,770	11/05/74	THEEUWES <i>et al.</i>			
	BG	3,811,444	05/21/74	HELLER <i>et al.</i>			
	BH	3,139,383	06/30/64	NEVILLE			
	BI	2,996,431	08/16/61	BARRY			
	BJ	2,799,242	07/16/57	WURSTER			

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	BK	WO 96/37202	11/28/96	PCT			X
	BL	WO 96/12477	05/02/96	PCT			X

OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>	
BM	Michael M. Coleman, et al., <u>Polymer</u> , 31:1187-1231, July 1990. "A Practical Guide to Polymer Miscibility"
BN	KODAMA KK, <u>DATABASE WPI</u> , AN: 94-068306, Derwent Publications Ltd., Jan. 18, 1994. "Sustained release preparation of oxybutynin chloride - comprises oxybutynin chloride, acidic substance, gelling agent and higher alcohol"
BO	KODAMA KK, <u>DATABASE WPI</u> , AN: 94-031722, Derwent Publications Ltd., Dec. 21, 1993. "Pharmaceutical preparations for prolonged action against urinary incontinence - comprise sustained release oxybutynin chloride for pharmaceutical compsn. sustained release coating film of non water soluble polymers and/or ethylcellulose"
BP	Enomoto, et al., <u>Chemical Abstracts</u> , 120(18):227011, May 2, 1994. "Sustained release preparation of oxybutynin chloride"
BQ	Enomoto, et al., <u>Chemical Abstracts</u> , 120(14):173499, April 4, 1994. "Sustained release formulations containing oxybutynin chloride"
BR	Julian H. Fincher, <u>J. Pharm Sci.</u> , 57(11):1825-1835, November 1968. "Particle Size of Drugs and Its Relationship to Absorption and Activity"
BS	P. Grafton, <u>Modern Plastics Encyclopedia</u> , 46:62-70, 1969. "General principles for designing with plastics"
BT	Suneel K. Gupta, et al., <u>Clinical Pharmacology & Therapeutics</u> , 61(2):Abstract PIV-26, 1997. "Evidence of Site Specific Presystemic Metabolism of Oxybutynin Following Oral Administration"
BU	K.W. Leong & R. Langer, et al., <u>Advanced Drug Delivery Reviews</u> , 1:199-233, 1987. "Polymeric controlled drug delivery"
BV	Robert J. Linhardt, <u>Controlled Release of Drugs: Polymers and Aggregate Systems</u> , Ch.2, pp.53-95, 1989. "Biodegradable Polymers for Controlled Release of Drugs"

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: AR02366USACON2	SERIAL NO.: TO BE ASSIGNED
INFORMATION DISCLOSURE STATEMENT FOR PATENT <i>(Use several sheets if necessary)</i>				APPLICANT: George GUITTARD, et al.	
				FILING DATE: Herewith	GROUP: to be assigned
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>					
	BW	S.M. Lu & Jun-Ying Yu, <u>Inter. J. Pharm.</u> , 112:117-124, 1994. "Dimensionless Presentation for Drug Release from a Coated Pure Drug Bead: 2 Experiment,"			
	BX	Carl Gustaf Nilsson, et al., <u>Neurourology and Urodynamics</u> , 16(6):533 542, 1997. "Comparison of a 10-mg Controlled Release Oxybutynin Tablet with a 5-mg Oxybutynin Tablet in Urge Incontinent Patients"			
	BY	<u>Remington's Pharmaceutical Sciences</u> , 14 th Edition, Ch.86 "Powders", pp 1626-1648, Mack Publishing Company, Easton, PA 1970.			
	BZ	<u>Remington's Pharmaceutical Sciences</u> , 17 th Ed., Ch 35, "Dissolution", pp 653-666, and Ch. 90, "Oral Solid Dosage Forms", pp. 1603-1625; Mack Publishing Company, Easton, PA 1985			
	<input checked="" type="checkbox"/> CA	Roerdink, et al., <u>Drug Carrier Systems</u> , 9:57-109, 1989.			
	CB	W.J. Roff et al., <u>Handbook of Common Polymers</u> , CRC Press, Cleveland Ohio, 1971.			
	CC	<u>The United States Pharmacopia - The National Formulary</u> , USP23:NF18, pp. 1791-1796, 1995. "<711> Dissolution"			
	CD	<u>The United States Pharmacopia - The National Formulary</u> , USP XXII / NF XVII, pp. 1578-1579, 1990. "<711> Dissolution"			
	CE	Dale E. Wurster, <u>J. Am. Pharm. Assoc</u> , 48(8):451-454, August 1959. "Air-Suspension Technique of Coating Drug Particles"			
	CF	Dale E. Wurster, <u>J. Am. Pharm. Assoc</u> , 49(2):82-84, February 1960. "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II"			
EXAMINER			DATE CONSIDERED		
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 98/01982

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K31/215

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 37202 A (ALZA CORP) 28 November 1996 see page 13 - page 18; examples 1-7 see claims ---	1-7
X	WO 96 12477 A (LEIRAS OY ; RANTALA PERTTI (FI)) 2 May 1996 "Results" see page 11 - page 12 see claims see figures ---	1-7
X	US 5 811 126 A (KRISHNAMURTHY THINNAYAM N) 22 September 1998 see column 12 - column 15; examples 11-19 --- -/--	1-7



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
 "E" earlier document but published on or after the international filing date
 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
 "O" document referring to an oral disclosure, use, exhibition or other means
 "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

14 April 1999

Date of mailing of the international search report

28/04/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Seegert, K

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE WPI Section Ch, Week 9409 Derwent Publications Ltd., London, GB; Class B05, AN 94-068306 XP002096606 & JP 06 009388 A (KODAMA KK) , 18 January 1994 see abstract</p> <p>---</p>	1-7
X	<p>DATABASE WPI Section Ch, Week 9404 Derwent Publications Ltd., London, GB; Class A96, AN 94-031722 XP002096607 & JP 05 339151 A (KODAMA KK) , 21 December 1993 see abstract</p> <p>---</p>	1-7
X	<p>GUPTA S.K. ET AL: "Evidence for Site-Specific Presystemic Metabolism of Oxybutynin Following Oral Administration" CLINICAL PHARMACOLOGY & THERAPEUTICS, vol. 61, no. 2, 1997, page 227 XP002099744 see the whole document</p> <p>---</p>	1-7
X	<p>NILSSON C.G. ET AL: "Comparison of a 10-mg Controlled Release Oxybutynin Tablet with a 5-mg Oxybutynin Tablet in Urge Incontinent Patients" NEUROLOGY AND URODYNAMICS, vol. 16, no. 6, 1997, pages 533-542, XP002099745 see page 539; figure 1 see page 540; table IV</p> <p>-----</p>	1-7

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 98/01982

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9637202	A	28-11-1996	US 5674895 A	07-10-1997
			AU 695194 B	06-08-1998
			AU 5639296 A	11-12-1996
			AU 9052298 A	14-01-1999
			BE 1009462 A	01-04-1997
			CA 2218714 A	28-11-1996
			DE 19681389 T	23-04-1998
			FR 2734483 A	29-11-1996
			GB 2318055 A	15-04-1998
			IT T0960427 A	21-11-1997
			NL 1003185 C	03-12-1996
			NL 1003185 A	25-11-1996
			NZ 307116 A	29-03-1999
			US 5840754 A	24-11-1998
WO 9612477	A	02-05-1996	AU 7994694 A	15-05-1996
US 5811126	A	22-09-1998	AU 7143796 A	28-04-1997
			CA 2207084 A	10-04-1997
			EP 0797435 A	01-10-1997
			WO 9712605 A	10-04-1997
			JP 10502390 T	03-03-1998

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/06639

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K31/215 A61K9/00 A61K9/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 399 359 (A. R. BAICHWAL) 21 March 1995 see the whole document ---	1-7
A	CHEMICAL ABSTRACTS, vol. 120, no. 18, 2 May 1994 Columbus, Ohio, US; abstract no. 227011, XP002010328 see abstract & JP,A,06 009 388 (KODAMA KK,JP) 18 January 1994 --- -/--	1-7

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

* & * document member of the same patent family

Date of the actual completion of the international search

7 August 1996

Date of mailing of the international search report

13. 08. 96

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Scarponi, U

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/06639

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>CHEMICAL ABSTRACTS, vol. 120, no. 14, 4 April 1994 Columbus, Ohio, US; abstract no. 173499, XP002010329 see abstract & JP,A,05 339 151 (KODAMA KK,JP) 21 December 1993</p> <p>-----</p>	1-7

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 96/06639

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5399359	21-03-95	AU-B- 6588894	18-09-95
		CA-A- 2161103	08-09-95
		CN-A- 1111507	15-11-95
		EP-A- 0700284	13-03-96
		FI-A- 955215	01-11-95
		HU-A- 72981	28-06-96
		WO-A- 9523593	08-09-95
